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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/039,789	03/16/1998	EDWARD LAWRENCE CARVER JR.	4537-01-2	9998

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EXAMINER
SODERQUIST, ARLEN

ART UNIT	PAPER NUMBER
1743	32

DATE MAILED: 04/11/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

MK - 32

Office Action Summary	Application No. 09/039,789	Applicant(s) CARVER ET AL.	
	Examiner Arlen Soderquist	Art Unit 1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 February 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *27-30,32-35,38 and 40-46* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *27-30,32-35,38 and 40-46* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

1. In view of the papers filed August 3, 1999, the inventorship in this nonprovisional application has been changed by the deletion of David Charles DeCava.

The application will be forwarded to the Office of Initial Patent Examination (OIPE) for issuance of a corrected filing receipt, and correction of the file jacket and PTO PALM data to reflect the inventorship as corrected.

2. The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claims 39-45 been renumbered 40-46. Claim 39 was presented in the amendment filed February 29, 2000 and cancelled in the amendment filed August 14, 2000.

3. Claims 27-30,32-35,38 and 40-46 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for making mixtures from at least two lysing agents by changing the respective volumes of the lysing agent relative to the volume of blood dependent upon the animal species of the blood, does not reasonably provide enablement for changing the lysing agent to blood volume ratio for a single lysing agent based on the type of animal species of the blood. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The instant specification teaches the presence of two lysing agents to make mixtures based on the animal type of the blood sample. Within the scope of these teachings, is using only one of the lysing agents to make the mixture for lysing the blood sample. However, the specification fails to teach that a single lysing agent can lyse all types of blood can by changing the blood to lysing agent volume ratio. The specification further fails to teach or provide any basis for grouping blood samples into a set or analyzing a set of blood sample types that can be lysed by changing the lysing agent to blood volume ratio of a single lysing agent. Due to the difference of blood types recognized by the art of record, one of skill in the art would not expect a single lysing

agent to be effective to lsye all blood types based on the teachings found in the instant specification. It also appears that a diluent is required to be present to form the lysing mixture since the lysing agents each have a constant concentration and the sensing apparatus requires a certain volume to run the analysis.

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in Graham v. John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 27-30,32-35,38 and 40-46 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Carver (US 5,316,725, newly applied). In the patent Carver teaches different compositions of lysing agents for performing white blood cell analysis. Column 13 discusses multispecies applications of the lysing agents teaching that due to variations in the physiology of the white blood cell membrane the lysing reagent composition must be optimized for each species. Table 1 shows the differences in the ratios of the two lytic agents in the composition, the amount of blood sample to the lytic composition, and the amount of diluent to the lytic composition for two species. Example 4 shows how to optimize the ratios by creating various mixtures from the individual lytic agents and diluent. In particular, table 3 shows a set of experiments in which the volume of the two lysing agents is varied. Since these experiments are being performed on an automated apparatus, the claims are anticipated. In the alternative, it would have been obvious to one of ordinary skill in the art at the time the invention was made to automate the process since the Courts have held that providing a mechanical or automatic means to replace manual activity which accomplishes the same result is within the skill of a routineer in the art (see *In re Venner*, 120 USPQ 192 (CCPA 1958)). Applicant is reminded that affidavits or declarations, such as those submitted under 37 CFR 1.131 and 37 CFR 1.132, filed during the prosecution of a parent application do not automatically become a part of this application. Where it is desired to rely on an earlier filed affidavit or declaration, the applicant should make copy of the original affidavit or declaration filed in the parent application.

7. Claims 27-30, 32-35, 38 and 40-46 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Yamamoto or Cellect Hematology in view of Carver (US 5,316,725 as explained above).

In the figures and associated discussion Yamamoto teaches an automated blood analyzer and method for making blood particle analyses. Yamamoto teaches at least one pump (102,111,162) in fluid communication with a mixing chamber (113-115) and a source diluent. A sample (101) is removed from a sample container by a sample probe

(117,161) and the at least one pump transfers the sample and diluent to the mixing chambers. Since the fluid flow arrows of figures 2 and 5 show pumps 102, 111, and 162 as capable of both suction and positive pressure, they are positive displacement pumps. Two different lysing reagents (141,142) are also transferred to the mixing chambers by a vacuum pump. The blood sample is analyzed for particles through a sensing orifice (158). The device has a controller (figure 3) for controlling the device and analyzing the result. Also Figure 4 shows that the result is obtainable in around 47 seconds. Yamamoto does not teach a multiple species database having different lysing compositions for each species that are mixed for blood samples from the different species.

In the figures and associated discussion Cellect Hematology teaches a fully automated blood analyzer and method for making blood particle analyses. In the figure on pages 5 - 6 Cellect Hematology shows the major systems of the instrument including at least one positive displacement syringe pump and stepper motor in fluid communication with a mixing chamber (dilution manifold) and a source diluent. A sample is removed from a sample container by a sample probe and the at least one pump transfers the sample and diluent to the dilution manifold. A lysing reagent is also provided during an analysis. The blood sample is analyzed for particles through a sensing orifice (counting manifold). The device has a controller (microprocessor) for controlling the device and analyzing the result. On page 1 in the first column, Cellect Hematology teaches the ease in adapting the instrument to add on new tests. Cellect Hematology does not teach a multiple species database having different lysing compositions for each species that are mixed for blood samples from the different species.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate software/database for multiple species including differences in lytic agents as taught by Carver into the Yamamoto or Cellect Hematology devices and methods and control the them to perform the optimum process for each different species because one of ordinary skill in the art would have recognized that the utility of the device would be increased by the ability to process blood from

multiple species and an optimized process including reagent sample compositions would have been required for each species as shown by Carver.

8. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection. The newly applied Carver reference has an inventorship that is different from the instant inventorship and clearly teaches the difference between blood of different animal species can be lsyed by changing the volume ratios between the blood sample and the lysing agent based on the animal species. In this respect the previous secondary references have been dropped because although they show that different concentrations of a single lytic agent (Dixon and Halliday) will have varying affects on blood samples of different species (canine and bovine), they do not teach that the concentration differences can be obtained by varying the volume ratio of blood to lytic agent. In the Halliday reference, both methods use the same volume ratio of blood to lytic agent and difference in concentration is obtained by varying the diluent that is also added to the blood sample.

The rejection for lack of enablement arises from the fact that the instant specification fails to teach one of skill in the art how to use a single lytic agent and properly lyse blood from all animal species based on changing the blood to lytic agent volume ratio. Since this is the broadest scope of the claims, it must be enabled by the specification. Additionally it appears that a diluent is also required for the proper functioning of the device and method since it appears that the apparatus and methods described in the specification require a minimum volume or a set volume of sample/lytic agent mixture for them to function properly.

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The cited art relates to measuring properties of animal blood.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arlen Soderquist whose telephone number is (703) 308-3989. The examiner's schedule is variable between the hours of about 5:30 AM to about 5:00 PM on Monday through Thursday and alternate Fridays.

For communication by fax to the organization where this application or proceeding is assigned, (703) 305-7719 may be used for official, unofficial or draft papers. When using this number a call to alert the examiner would be appreciated. Numbers for faxing official papers are 703-872-9310 (before finals), 703-872-9311

(after-final), 703-305-7718, 703-305-5408 and 703-305-5433. The above fax numbers will generally allow the papers to be forwarded to the examiner in a timely manner.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

Arlen Soderquist

April 10, 2002

ARLEN SODERQUIST
PRIMARY EXAMINER